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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,207	03/16/2004	Bey-Dih Chang	SEN-001US3	3124

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,207	CHANG ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment and response to restriction requirement filed 10/4/06.

Election/Restrictions

Applicant's election of Group I (claims 1-3 and 6-8) in the reply filed on 10/4/06 is acknowledged. The election of Fibronectin 1 in response to the species requirement in the reply filed on 10/4/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon reconsideration, the restriction requirement between Groups I and III and II and IV has been dropped. As well, the species election has been extended to include Plasminogen activator inhibitor type I as this species has been identified in the art.

Claim Objections

Claim 1 is objected to because of the following informalities: in line 1, the word "associate" should be -- associated--.

Claim 1 is drawn to non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of "(a) contacting a mammalian cell in the presence or absence of the compound with an agent that induces senescence or culturing the mammalian cell under conditions that induce senescence" are unclear. The dependent claims are included in the rejection because they fail to address or clarify the basis of the rejection as discussed in detail for the independent claims. It appears that 1) the cells in the presence or absence of the compound to be tested are contacted with an agent **or** 2) the cells are cultured under conditions that induce senescence. In the case of scenario (2) induction of senescence is used to induce CDK inhibitor expression, however there is no test compound used under these conditions. Therefore under conditions #2, it is not clear how compounds are identified that inhibits CDK inhibitor mediated induction of cellular gene expression.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Beug et al (US 6,383,733; see entire document) as evidenced by Yu et al (J Neuroimmunology, 2000, pages 2-10) and Tremain et al (Oncogene, 2000, page 1698-1709).

Beug et al teach culturing of a mammalian cell comprising a reporter gene fused to the plasminogen activator inhibitor promoter in the presence and absence of pharmaceutical compositions and with TGFβ (see e.g. figure 18). Following this gene expression of the reporter gene is assayed. As evidenced by Yu et al (see e.g. page 8, col 2), TGFβ is an inducer of senescence and p21. Furthermore, p21 induces PAI as evidenced by Tremain et al (see e.g. page 1706, col 1). Therefore, a mammalian cell comprising a gene induced by p21, PAI-reporter, is treated with TGFβ, an inducer of senescence in the presence and absence of compounds. Identification of an inhibitor of reporter gene expression (see e.g. figure 18) identifies inhibitors of the induction of this gene and inhibitors of p21 and senescence inherently. This method is intended as a screen to identify agents that inhibit TGFβ mediated expression from the reporter gene construct (see e.g. col 11, line 50-61). Reporter gene expression was detected by assaying activity of the cellular gene product as recited in claim 7.

Claims 1, 2, 6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Fisher and Jiang (US 6,051,376; see entire document).

Fisher and Jiang propose methods of identifying inhibitors of senescence (see e.g. col 17, line 45-50). The methods involve culturing a plurality of cells with a compound and assaying for expression of MDA7 as a marker. Method of assaying includes using immunological agents and

hybridization (see e.g. figure 4 and col 58, line 28-64). MDA7 it is taught is induced by induction of senescence (see e.g. col 98, line 8-30), which is also associated with induction of p21 or mda6 (col 109, line 25-38). Identification of an inhibitor of MDA7, through identification of muted MDA7 expression, results in identification of inhibitors of p21 and senescence inherently. Therefore, Fisher and Jiang anticipate the method as recited in instant claims 1, 2, 6 and 8. As well, applicants teach that Fibronectin is assayed following induction of senescence (conditions of IFNβ and MEZ).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher and Jiang (US 6,051,376; see entire document) as applied to claims 1, 2, 6 and 8 above, and further in view of Porter et al (J Cell Physiology, 1992, pages 545-551; see entire document).

Applicants claim a method of identifying inhibitors of senescence by assaying for expression of fibronectin XO2761.

The teachings of Fisher and Jiang are described above and are applied as before except;

Fisher and Jiang do not teach that Fibronectin I is assayed as a marker for inhibition of senescence.

Porter et al teach that human fibronectin (absent evidence to the contrary, this is Fibronectin I and as evidenced by XO2761) is assayed using SEN-1, SEN-2 and SEN-3 as markers of senescence (see e.g. abstract). Porter et al teach that SEN antibodies react with fibronectin from a variety of cells and are useful markers for senescence. Multiple species were assayed and the antibodies were found to be universal for a variety of fibronectins from human. XO2761 is distinguishable by being from human.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assay for inhibitors of senescence using the methods taught by Fisher and Jiang using Fibronectin I as a marker as taught by Porter et al because Fisher and Jiang teach that it is within the ordinary skill of the art to induce senescence and assay for induction of gene expression of senescence related genes and then to identify inhibitors of senescence and because Porter et al teach that it is within the ordinary skill of the art to use human fibronectin as a marker for senescence detectable by SEN antibodies. One would have been motivated to do so in order to receive the expected benefit of ease of detection from a variety of cells coupled with the ease of detection demonstrated by Porter et al. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 6-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims. That is, claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, U.S. Patent No. 6, 706,491 and the instant claims recite a method comprising treatment of a mammalian cell such that p21 is induced (the instant claims recite that senescence is induced which is a p21 related event) and then assay for genes induced by p21 in the presence and absence of test compounds. The method of the instant claims identifies

inhibitors of senescence, which is inherent in the method of U.S. Patent No. 6, 706,491 that identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from U.S. Patent No. 6, 706,491, then two different assignees would hold a patent to the claimed invention of U.S. Patent No. 6, 706,491, and thus improperly there would be possible harassment by multiple assignees.

Claims 1-3 and 6-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-37 and 58-63 of copending Application No. 10/233,032.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 28-37 and 58-63 of copending Application No. 10/233,032. That is, claims 28-37 and 58-63 of copending Application No. 10/233,032.anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, copending Application No. 10/233,032 and the instant claims recite a method comprising treatment of a mammalian cell such that p21 is induced (the instant claims recite that senescence is induced which is a p21 related event) and then assay for genes induced by p21 in the presence and absence of test compounds. The method of the instant claims identifies inhibitors of

senescence, which is inherent in the method of U.S. application 10/233,032, which identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 10/233,032, then two different assignees would hold a patent to the claimed invention of 10/233,032, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3 and 6-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30, 32, 33, 52-58, 95-101, 103-105 and 107-115 of copending Application No.09/861925.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims. That is, claims 25-30, 32, 33, 52-58, 95-101, 103-105 and 107-115 of copending Application No.09/861925 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, application 09/861,925 and the instant claims recite a method of identifying a compound that inhibits induction of genes using a cell comprising a gene induced by p21 under conditions that induce senescence. The method of the

instant claims identifies inhibitors of senescence, which is inherent in the method of U.S. application 09/861925, which identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from 09/861925, then two different assignees would hold a patent to the claimed invention of 09/861925, and thus improperly there would be possible harassment by multiple assignees.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633